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Aldicarb: Position Document 2/3. Preliminary Determination to Cancel Registrations of Aldicarb Products and Availability of Technical Support Document; Notice

(U.S.) Environmental Protection Agency, Washington, DC

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16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

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Part IV

Environmental Protection Agency

Preliminary Determination to Cancel Registrations of Aldicarb Products and Availability of Technical Support Document; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/39A; FRL-3407-2]

Preliminary Determination to Cancel Registrations of Aldicarb Products and Notice of Availability of Technical Support Document

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of preliminary determination.

SUMMARY: This Notice sets forth EPA's preliminary determination regarding the continued registration of pesticide products containing aldicarb and EPA's assessment of the risks and benefits associated with the pesticidal uses of aldicarb. This Notice announces EPA's plan for protecting the nation's ground water from contamination by the registered uses of aldicarb through lable requirements, monitoring, and State Management Plans. This Notice also announces the availability of the Aldicarb Technical Support Document. The Technical Support Document and supporting scientific reviews constitute the technical documents in support of this action.

DATE: Written comments should be received on or before September 27, 1988.

ADDRESS: Submit three copies of written comments, bearing the document control number "OPP-30000/39A" by mail to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 246, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this Notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked CBI may be publicly disclosed by EPA without prior notice to the submitter. All written comments and the correspondence index will be available for public inspection and copying in Rm. 236 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bruce A. Kapner, Special Review Branch, Registration Division (TS-767C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1006, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. (703) (557-5493).

Copies of the Aldicarb Technical Support Document are available from the contact person at the address given above.

SUPPLEMENTARY INFORMATION: This Notice is organized into seven Units. Unit I provides a summary of EPA's proposed actions to regulate the use of aldicarb to prevent or reduce the contamination of ground water. Unit II provides background information on aldicarb and the regulatory history. Unit III provides the legal background. Unit IV provides a summary of the risk and benefit determinations and proposed regulatory actions. Unit V sets forth procedural matters. Unit VI discusses the opportunity for public comment and Unit VII includes information on the Public Docket.

I. Summary of EPA's Proposed Actions

A. Objective

EPA is proposing a new pesticide management approach to prevent unacceptable ground water contamination from the use of aldicarb. The objective of this proposed decision is to manage the use of aldicarb through a variety of both nationally uniform and geographically-specific measures in areas of the country where ground water is vulnerable to contamination. EPA views this proposed decision for aldicarb as the first "real world" illustration of its strategy for addressing its concern for pesticides in ground water.

The key aspect of this new approach is its major emphasis on a strong lead management role by those states where EPA has determined ground water resources are potentially the most vulnerable to unacceptable levels of aldicarb. EPA prefers that these states develop and implement plans to tailor pesticide management measures to specific local ground water protection needs. Acceptable pesticide management plans will serve as the basis for the continued registration of aldicarb within these designated states. EPA believes that such a strong lead management role by the states has the greatest potential for protecting ground water resources while providing for the continued benefits of aldicarb's use through proper management.

B. Background

Aldicarb is an insecticide/nematicide which is registered for use on 14 crops. It is an acutely toxic pesticide which can cause reversible cholinesterase inhibition. Laboratory data both on animals and humans, as well as human incident data, indicate that extremely low levels of aldicarb exposure can produce toxic effects in humans.

Aldicarb has been detected in the ground water of 48 counties of 16 states at levels ranging from 1 to over 500 parts per billion (ppb). EPA's Office of Drinking Water has established a Health Advisory level, the level of exposure in drinking water at which it has been determined that the public health is adequately protected, of 10 ppb for aldicarb. Aldicarb residue levels have been found to exceed the Health Advisory in 25 counties of 11 states.

EPA is concerned with the presence of aldicarb in the nation's ground water and with the potential risks resulting from drinking water contaminated with aldicarb. Although it is not possible to predict the exact number of people potentially exposed to unacceptable levels of aldicarb in their drinking water, EPA can identify those areas which are most vulnerable to leaching by aldicarb. It is in these areas that EPA believes major management efforts are needed if the registrations of aldicarb are to be continued.

Aldicarb is an important agricultural pesticide used on a number of crops including citrus, potatoes, cotton, and peanuts. Without the availability of aldicarb, growers could experience increased production costs to control pests. Consumers could also expect to pay higher prices for some food products. EPA has concluded that on a national basis, the risks posed by aldicarb contamination of ground water outweight the benefit of use.

EPA believes that it is possible to reduce the risks significantly by imposing certain regulatory restrictions short of cancellation of all use. EPA believes that such restrictions would reduce exposure to a point where the remaining benefits would outweigh the risks of use.

C. EPA's Proposals

EPA's proposed approach for aldicarb implements the recently proposed long-term strategy addressing the concern of pesticides in ground water. This aldicarb proposal uses graduated measures in order to prevent unacceptable ground water contamination. The extent of preventive measures required in a specific area

would depend on the area's vulnerability to such contamination. The most stringent prevention measures would be required in those areas where there is the greatest potential for unacceptable levels of ground water contamination by aldicarb.

1. National Measures

EPA is proposing uniform, national actions which would prohibit the use of aldicarb within 300 feet from any drinking water well and classify aldicarb as a restricted use pesticide due to ground water concerns. These measures would serve as baseline requirements in all areas where aldicarb is used. In addition to these baseline efforts, monitoring would be required in representative areas which have been evaluated in EPA's ground water assessment as having a medium potential to leach. The data resulting from this monitoring will be used to further characterize the medium areas and to determine whether additional regulatory action beyond the baseline requirements will be needed in these areas.

2. Area-specific Measures

The most stringent measures EPA is proposing are in those areas identified as having the greatest potential for aldicarb to reach ground water. States would play an active role in protecting ground water resources in these areas by implementing State Pesticide Ground Water Management Plans. EPA believes that the States are in the best position to regulate the use of aldicarb to prevent/reduce unacceptable ground water contamination in the areas of greatest concern. Acceptable State Management Plans will serve as the basis for the continued registration of aldicarb within these highly vulnerable areas.

EPA is proposing two options for identifying the areas which would need a Management Plan. One option is based on a method which evaluated 11 hydrogeologically similar areas called Heath Regions. The other option is based on a county evaluation method. If the option based on the Heath Region assessment were used, the following states would be required to submit a plan: Alabama, Florida, Georgia, Maine, Michigan, Mimesota, New York, North Dakota, Pennsylvania, and Wisconsin. If the option based on the county assessment were used, criteria would be applied to identify which counties required a plan. To date, EPA has applied the county assessment method to only 4 states with the following results: 3 out of 58 counties in California, 26 out of 67 counties in Florida, 8 out of 72 counties in Wisconsin and no counties in North Carolina would need to develop and implement a Management Plan. EPA anticipates that 15 to 24 states would be required to submit plans for one or more counties if the county option were chosen.

D. Issues for Public Comment

The regulatory approach proposed by EPA represents a new way to manage pesticides. The problems posed and issues raised by pesticides which leach are different from the pesticide problems and issues traditionally dealt with by EPA. Although EPA believes the approach it has proposed is a viable means of dealing with the concerns of leaching, it is receptive to any suggestions on how it can be improved or refined. Accordingly, public comment is being solicited on a number of questions and issues pertaining to the actions proposed. Specifically, EPA is soliciting comment on the following:

(1) Which option for identifying those areas which need Management Plans is favored, the Heath Region or county approach?

(2) What should be the components of a Management Plan?

(3) Should a localized risk/benefit analysis be performed and, if so, how should it be performed and who should do it?

(4) Who should bear the responsibility for cleaning up ground water if contamination occurs?

(5) Should EPA attempt to establish restrictions based on the hydrogeology of a particular site (e.g., soil type or pH of the soil) to prevent contamination of ground water?

(6) Should EPA impose Management Plans through the rulemaking process or the Special Review process?

II. Background and Regulatory History

Aldicarb is a soil incorporated carbamate pesticide absorbed by plant roots. It provides systemic control of insects, mites and nematodes. EPA estimates that approximately 5.2 to 5.7 million pounds active ingredient (a.i.) are used annually. Rhone-Poulenc AG Company is the sole registrant of aldicarb. Since its first registration in 1970 for use on cotton, aldicarb is now registered for use on: Citrus, dry beans, grain sorghum, ornamentals, pecans, peanuts, potatoes, seed alfalfa, soybeans, sugar beets, sugarcane, sweet potatoes and tobacco.

Aldicarb is an acutely toxic pesticide, causing reversible cholinesterase inhibition. Laboratory data both on animals and humans, as well as human incident data, indicate that extremely low levels of aldicarb exposure can produce toxic effects in humans.

On July 11, 1984, EPA issued a Notice of Rebuttable Presumption Against Registration (RPAR, now called Special Review) and Continued Registration of Pesticide Products Containing Aldicarb (49 FR 28320). That action was based on a finding that registrations of pesticide products containing aldicarb met or exceeded risk criteria in 40 CFR 162.11(a)(6)(i) which provide that a Special Review shall arise if it appears that, "based on toxicological data, epidemiological studies, use history, accident data, monitoring data, or such other evidence as is available to the Administrator, the pesticide may pose a substantial question of safety to man or the environment * * *" The basis for the initiation of the aldicarb Special Review was the potential for unreasonable adverse effects, specifically acute toxic effects to humans from dietary exposure to drinking water from ground water wells contaminated with aldicarb. Subsequently, the potential risks due to dietary exposure to aldicarb-treated crops was also examined.

As a part of the Special Review process, EPA evaluates the risks and benefits associated with the use of a pesticide and then proposes any regulatory actions necessary to assure that use of that pesticide results in no unreasonable adverse effects.

Potential risks are associated with consumption of raw agricultural commodities and drinking water contaminated with residues of aldicarb. Aldicarb has been detected in drinking water wells in 16 states at levels ranging from under 10 parts per billion (ppb) to over 500 ppb and, because aldicarb residues can persist in ground water for several years, ground water contamination by aldicarb may be a widespread, long-term problem.

EPA's position and regulatory rationale are set forth in Unit III of this notice. The basis for EPA's action is explained more fully in the Aldicarb Technical Support Document. The Technical Support Document also contains references, background information, and other information pertinent to the registration of pesticide products containing aldicarb. The Aldicarb Technical Support Document and this Notice will be sent to all registrants and applicants for registration of pesticide products containing aldicarb.

If EPA concludes that the risks of a pesticide outweigh its benefits, the administrative mechanism under FIFRA which EPA uses to require registrants to either adopt risk reduction measures or face cancellation is the Notice of Intent

to Cancel. A draft Notice of Intent to Cancel aldicarb products which imposes EPA's risk reduction measures will be prepared following the receipt and analysis of comments submitted in response to this Federal Register Notice. The draft Notice of Intent to Cancel will be forwarded to the Scientific Advisory Panel, the Secretary of Agriculture, and to the registrant of pesticide products containing aldicarb to permit their review. A copy of the draft Notice of Intent to Cancel will also be placed in the public docket. The draft Notice will contain provisions regarding procedures for requesting a cancellation or denial hearing after issuance of a final Notice of Intent to Cancel, assuming that registrants do not commit to implement the risk reduction measures proposed here.

Comments on this Federal Register Notice and the Technical Support Document must be filed within 90 days of the publication of this Notice.

III. Legal Background

A. The Statute

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a product can be registered unconditionally, it must be shown that it can be used without "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)), that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" (FIFRA section 2(bb)). The burden of proving that a pesticide meets this standard for registration is at all times on the proponents of registration and continues as long as the registration remains in effect. If at any time EPA determines that a pesticide no longer meets this standard for registration, then the Administrator may cancel the registration under FIFRA section 6.

B. The Special Review Process

The term "Special Review" is the name being used for the process previously called the Rebuttable Presumption Against Registration (RPAR) process (40 CFR 162.11). Modifications to the process are described in the final Special Review regulations (40 CFR Part 154). These regulations, promulgated on November 19, 1985 (50 FR 49003), became effective on May 14, 1986.

The Special Review process provides a mechanism to:

(1) Gather information about the risks and benefits of pesticides which appear to pose unreasonable risks to man and the environment.

(2) Publicly state EPA's position.

(3) Invite pesticide registrants, other Federal and state agencies, user groups, environmental groups, and other interested persons to comment on EPA's review of a pesticide.

(4) Establish a public docket.

(5) Review and respond to all significant comments submitted in a timely manner.

(6) Make a final regulatory decision based on a balancing of risks and benefits associated with a pesticide's use.

Issuance of this Notice means that EPA has assessed the potential adverse effects and benefits associated with the use of pesticide products containing aldicarb and that EPA has preliminarily determined that, unless the terms and conditions of registration are modified as proposed in this Notice, the risks from the use of pesticide products containing aldicarb outweigh the benefits of such use.

IV. Summary of Risk and Benefit Determination and Proposed Regulatory Action

A. Determinations on Toxicity

Aldicarb has a high acute toxicity to humans via the oral, inhalation and dermal routes of exposure and has been assigned to toxicity category I, based on all three routes of exposure. It is a potent cholinesterase inhibitor with an acute LD_{50} in rats of 0.9 mg/kg. In a study using human test subjects, the Lowest Observed Effect Level (LOEL) for clinical signs (e.g., gastrointestinal disturbances, unconsciousness, blurred vision, excessive salivation, seizures, and disorientation) is 0.1 mg/kg and the No Observed Effect Level (NOEL) for clinical signs is 0.05 mg/kg. There was no NOEL for cholinesterase inhibition in the registrant's human study; the lowest doses of aldicarb tested, 0.025 mg/kg., caused a 35 to 54 percent decrease in cholinesterase levels. The National Academy of Sciences used these data to extrapolate a NOEL of 0.01 mg/kg for cholinesterase inhibition.

No known reports of cholinesterase inhibition and/or clinical signs have been reported as a result of legal application of aldicarb. A number of reports of accidental exposures following misuse of aldicarb indicate that cholinergic signs, even severe cholinergic signs, may occur at doses considerably below 0.1 mg/kg, the LOEL for clinical signs in the human study described above. These effects are reported to occur at doses as low as 0.0026 mg/kg. These data are anecdotal, however, and it is difficult to precisely quantify exposures for these accident data. The data may indicate a broad range of sensitivity to oldicarb's acute effects. In light of all information, EPA believes that the NOELs for cholinesterase inhibition and clinical signs associated with such inhibition are close to 0.01 mg/kg and at 0.001 mg/kg it is unlikely that individuals will show clinical signs or have depressed cholinesterase activity.

The chronic toxicity data base for aldicarb is complete. Aldicarb is negative for delayed neurotoxicity, oncogenicity and reproductive effects. It is also negative for teratogenicity. The one effect of concern is acute cholinesterase inhibition. There is a 10 ppb Health Advisory level for aldicarb residues that contaminate drinking water, based on the cholinesterase inhibition seen during chronic exposure. The Health Advisory is set by EPA's Office of Drinking Water, is based on consideration of risks, and reflects that Office's judgment that exposures to residues of aldicarb in drinking water above the Health Advisory would not protect human health adequately.

B. Ground Water Vulnerability Analyses

The objective of the ground water vulnerability analyses is to determine those areas of the country where there is a high, medium, or low potential for ground water to be contaminated from the use of aldicarb. Due to the length and extensive technical scope of these analyses, they are summarized and only a portion of the scientific details and documentation have been included in this Notice. The Aldicarb Technical Support Document contains a more detailed discussion of the vulnerability assessments. The supporting references for the assessments can be viewed in the Public Docket, located in room 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia.

1. Environmental Fate

Aldicarb is mobile in most types of soil in which it is applied. Incidents of ground water contaminated by aldicarb, however, have been primarily associated with sandy soils. Aldicarb binds poorly to sandy soils (sands, loamy sands, and sandy loams, primarily) and any water input to sandy soil (i.e., rain and irrigation) tends to recharge rapidly through the profile, carrying aldicarb with it.

Aldicarb oxidizes to aldicarb sulfoxide and a portion of the aldicarb

sulfoxide oxidizes to aldicarb sulfone. Aldicarb sulfoxide and sulfone residues are found approximately in a one-to-one ratio. The oral LD^{50} of aldicarb sulfoxide is 0.9 mg/kg, the same as for aldicarb, while aldicarb sulfone is much less toxic, with an LD^{50} of 24 mg/kg.

Soil half-lives for degradation of aldicarb and its metabolities to nontoxic residues in the root zone vary from a week to greater than 2 months, but are typically between 1 and 2 months. The primary mode of degradation in the root zone is oxidative metabolism by microorganisms, although hydrolysis may also occur. Factors which result in more rapid rates of aldicarb degradation in the root zone include warm soil temperatures, high soil moisture content, and high organic matter content.

The primary mode of degradation below the root zone is chemical hydrolysis. Typically, the rate of degradation by hydrolysis is slower than microbial degradation. Measured and extrapolated half-lives vary from several weeks to greater than 20 years under ambient conditions, depending on pH and temperature.

2. Ground Water Assessment

EPA does not believe that methods presently exist to perform accurate quantitative assessments of the amount of a pesticide which may appear in ground water. Thus, EPA's review provides a qualitative, rather than quantitiative, assessment of the vulnerability of ground water to aldicarb contamination.

In order to determine the relative potential for aldicarb to leach and contaminate ground water in different parts of the United States, EPA used two geographic units of evaluation: One involving Health Regions (11 distinct hydrogeologic ground water regions of the United States, developed by the U.S. Geologic Survey) an done involving counties. A brief discussion of the two approaches follows.

a. Ground Water Assessment by Health Region.

This assessment evaluates the potential for aldicarb to reach ground water as a result of its use on the major aldicarb crops—citrus, potatoes, cotton, soybeans, and peanuts. Those crops account for over 90 percent of aldicarb use. The methodology developed was intended to identify the most vulnerable situations.

Eleven of the Health Regions were deemed appropriate for examination based on extent of crop acreage of the five chosen crops in the regions. This structuring resulted in 32 crop/region combinations which were evaluated for their potential for aldicarb contamination of ground water aldicarb usage.

Three major parameters were employed to evaluate the ground water vulnerability of these regions: hydrogeologic characteristics of counties, ground water monitoring data, and crop use practices. Hydrogeologic characteristics were evaluated by a close evaluation of 138 counties where aldicarb is used, and use of a hydrogeologic model called DRASTIC. DRASTIC is a screening system which estimates ground water vulnerability using seven characteristics: Depth to ground water; recharge; aquifer media; soil media, topography; impact of the vadose zone and hydraulic conductivity of the aquifer. Crop use practices include cultivation methods, rate of application, and temperature for each of the five major crops grown in a particular region.

Each of the parameters was given a qualitative rating of high, medium, or low each crop/region combination. A weight-of-evidence approach was then used to evaluate each crop/region combination as high, medium, or low potential to contaminate ground water.

The overall ground water vulnerability ratings, based on these independent parameters, show a high vulnerability for areas growing potatoes in the Northeast and Midwest and citrus and peanuts in the Southeast. In the first three of these crop/regions, monitoring data have confirmed the vulnerability rating. In the case of areas growing peanuts in the Southeast, the county, DRASTIC, and site-specific analyses indicated a high vulnerability, although monitoring data comparable to that performed in other regions were not available.

Cotton growing areas in the West Coast and Southwest show a low vulnerability due primarily to the low application rates and the deep ground water associated with these regions.

The remaining crop/region combinations were given medium vulnerability ratings based on the parameters. A portion of these medium crop/region could be placed in the high or the low vulnerability category if additional monitoring data were available.

EPA believes that this weight-of-evidence approach and corresponding qualitative ground water vulnerability ratings provide a rational basis for depicting potential ground water contamination from aldicarb usage.

b. Ground Water Assessment by County

Another approach developed by EPA to predict the likelihood of ground water contamination was to perform an assessment at the county level using basically the same parameters as the Health Region approach. However, instead of crop practices, the county assessment approach employed use rates and/or total amount of aldicarb applied in a county. The advantage to the county approach is that it focuses on a smaller geographic unit than the Health Region approach.

This approach can be used to predict the likelihood of ground water contamination by aldicarb within a county. The parameters would be qualitatively rated and each of the counties would be classified as having a high, medium or low potenital for ground water contamination. EPA has performed the county ground water assessment for all counties in four selected states (California, Florida, North Carolina, and Wisconsin). In the example of the 4 state analysis, California has 3 out of 58 counties, Florida has 26 out of 67 counties, and Wiconsin has 8 out of 72 counties rated as high. North Carolina did not have any counties which were ranked high. However, the vulnerability to ground water contamination was sufficiently high in all other counties in each of these four states to be classified as medium in vulnerability.

As in the Health Region assessment, EPA believes that the weight-of-evidence approach and corresponding qualitative leaching potential ratings provide a rational basis for depicting ground water vulnerability to aldicarb contamination.

C. Risk Conclusions

1. Risks From Treated Commodities.

EPA has estimated dietary exposure to aldicarb, resulting from a single exposure, from consuming treated food commodities. EPA used data in support of tolerances submitted by the registrant and FDA market basket survey data to estimated exposure. Two commodities, potatoes and citrus, were identified as causing potential concern regarding risks to consumers. However, EPA has encouraged pesticide registrants to conduct monitoring studies to give an empirical representation of the level of pesticide residues to which the public is exposed. The registrant has recently submitted the results of a National Food Survey which monitored for residues of aldicarb in the market place. These data are currently under review and will be used, along with the tolerance data and the FDA market basket survey data, in the final dietary risk assessment.

2. Risks From Contaminated Drinking Water

EPA has estimated the percent of the population consuming various quantities of drinking water in their diet. EPA has also calculated a dose of aldicarb and provided a Margin of Safety estimate for these populations assuming various levels of contamination. The focus of the analysis was on the population of greatest risk, infants, because they consume most of their diet as formula and fruit juice which are both frequently prepared using tap water. EPA calculated that when drinking water containing aldicarb at 10 ppb, as many as 13 percent of consuming infants could be exposed to a dose of 0.001 mg/kg or greater of aldicarb. Clearly not all ground water in the nation contains aldicarb, nor where contamination is found will it always be above 10 ppb; see discussion in Unit IV.E. The corresponding Margin of Safety for cholinesterase inhibition would then be 10 or less, based on the NOEL estimated by the National Academy of Sciences.

It is difficult for EPA to perform a quantitative risk analysis because of the limited scientific understanding of ground water contamination. Traditionally, quantitative risk analyses have been conducted to assess the impact of various regulatory mechanisms designed to reduce dietary exposure from consumption of treated crops and/or applicator exposure. Data are available or can be generated which can provide fairly accurate estimates of the levels of likely dietary or applicator exposure. This is not the case for assessing exposures for pesticide contamination of ground water. While available data allow EPA to predict those conditions for which there exists the greatest potential for aldicarb to reach the ground water, EPA has a limited ability to estimate levels and length of exposure or the size of the exposed population. One of the key problems is EPA's inability to make general statements, on a national or local basis, about the proximity of drinking water wells to fields where aldicarb is used. Given the low level at which there is a risk from drinking water contaminated with aldicarb and the numerous areas in which aldicarb has already been detected, EPA is concerned in all instances where leaching appears likely to occur.

D. Determination on Benefits

After a thorough review of comments received in response to the Position Document 1 and subsequent attempts to obtain specific data, EPA determined that data sufficiently detailed to prepare a highly quantitative analysis of aldicarb benefits on a site/pest basis are limited. Data on the minor use sites were generally incomplete or unavailable. As a result, the analysis presented in the Aldicarb Technical Support Document often rely on the judgment and estimates provided by experts knowledgeable about various cropping practices and aldicarb use. Field tests comparing efficacy and performance of aldicarb and alternatives were unavailable for many site and pest combinations. Registrant and user data for comparative performance are solicited for all use sites.

If aldicarb registrations are cancelled, producer/grower control costs could increase by an estimated $54 to $85 million annually. Significant impacts are expected for citrus ($54 million) and peanuts ($17 to $33 million). Significant user losses and consumer expenditure impacts are expected as a result of lower citrus production. Moderate impacts at the national level are expected for cotton ($20 to $29 million) and potatoes ($11 to $15 million). Total producer and consumer impacts are estimated to be $135 million.

In addition to these tangible benefits, a number of existing benefits are difficult to quantify. Aldicarb simultaneously controls nematodes, mites and insects, especially if applied at the higher nematicidal application rates. Many alternatives cannot provide simultaneous control of these three pests without being used in combination with other pesticides. The systemic action of aldicarb provides residual pesticide effects. Many alternatives, by contrast, are applied as foliar sprays and provide a shorter duration of pest control. Alternatives must be applied two, three, or more times to provide equivalent pest control. Aldicarb is applied as a soil incorporated granule, while most of the probable alternatives are applied as sprays. Alternatives are, therefore, more subject to off-target drift and attendant mixer/loader/applicator exposure. In summary, no single alternative will completely replace aldicarb, although combinations and multiple treatments by these alternatives can provide effective control, albeit at higher costs.

Many of the alternatives have an insufficient toxicological data base. These data will be, or are currently being produced in response to EPA's reregistration process. Aldicarb is more acutely toxic to humans than any of the alternatives; however, the acute toxicity of some alternatives differs by less than one order of magnitude from aldicarb. Aldicarb has demonstrated a potential to leach, posing additional concern. Some of the alternatives to aldicarb have been found to be contaminants in ground water. On the other hand, other alternatives have been identified as oncogens, mutagens, or teratogens, while aldicarb has been found to be negative in these three categories.

E. Risk/Benefit Analysis

This Unit identifies and analyzes the most appropriate regulatory options for use of aldicarb. To accomplish this, the risks of use are compared with the benefits of use.

EPA is deferring a crop-based dietary risk assessment of aldicarb in order to complete its review of the data from the registrant's food survey. The final data have been submitted and are currently being evaluated. After the data are reviewed, EPA will conduct a risk/benefit analysis based on risks from consumption of contaminated food crops.

As previously explained, people are at risk from consuming water contaminated with aldicarb residues. Although it is not possible at this time to generate reliable quantitative estimates of either the levels of exposure to contaminated ground water or the number of people exposed to such contamination, some information exists which enables EPA to put the risks associated with ground water contamination into perspective. The extent of aldicarb contamination of ground water is significant. Thousands of wells have been contaminated with detectable levels of aldicarb. EPA evaluated studies which comprise over 35,000 samples of ground water from some vulnerable areas. Nearly one-third of all samples in these studies evaluated were positive, and over one-half of the positive samples exceeded the Health Advisory.

Many areas of the country where aldicarb is used are vulnerable to contamination and not all of these areas have been sampled. Therefore, it is reasonable to assume that there are other wells which have been contaminated by aldicarb but which have not yet been identified.

Using either the Heath Region or county approach assessing ground water vulnerability, EPA can target areas where there is the greatest possibility of aldicarb leaching to ground water.

Complicating the risk/benefit analysis in this case is the difficulty of placing a value on ground water. EPA believes that ground water is a valuable resource and that its protection from unacceptable contamination is

extremely important. Once contaminated, clean-up of an aquifer is exceptionally expensive or technically difficult, especially if the contamination is at a low level and widespread. If an alternate water source is to be provided, it can be both costly and inconvenient.

Available information indicates that the eventual cost of preventing exposure to drinking water contaminated with unacceptable levels of aldicarb could be quite sizable. Ground water contamination in Suffolk County, New York, serves as an example of how significant these costs can be. Since 1980, granular activated carbon treatment units have been installed in 3104 households where the water supply had been contaminated by aldicarb above 7 ppb. (The New York State Health Department established 7 ppb as the allowable guideline level for aldicarb residues in drinking water.) The cost of each filter is approximately $600 and the costs of installation are about $100. On the average, each filter is effective for 1 year after which time it must be replaced. The costs for a replacement filter and for installing it are about $150. The total costs for filters and the initial installation for Suffolk County is approximately $2.2 million with annual replacement costs of $465,000.

EPA believes that the total cost of cleaning up contaminated wells on a national basis could approach or even exceed the total benefits of aldicarb which have been estimated up to $135 million a year. Obviously, clean-up costs are not the only measure of risk, since some exposure would occur before filters are installed for a water supply. In light of all potential risks, therefore, EPA concludes that the risks posed by consuming water contaminated by aldicarb above the Health Advisory outweigh the benefits of use.

EPA has analyzed the risks of aldicarb resulting from ground water contamination, as well as the associated benefits, and concludes that use of aldicarb generally causes unreasonable adverse effects on the environment. Given the widespread incidence of contamination and the extensive presence of aldicarb in vulnerable areas, it could be appropriate to cancel the use of aldicarb nationally. There are, however, regions with low ground water contamination potential due to hydrogeologic formations or certain crop practices. Prohibition of aldicarb use in these areas may not be warranted because the risks would not outweigh the benefits of continued use. Similarly, minimal risk reduction measures in medium vulnerability areas may be sufficient for benefits to outweigh risks. EPA believes that the greatest risks are associated with aldicarb use in areas where the ground water is highly vulnerable to contamination. By prohibiting or actively managing the use of aldicarb in those vulnerable areas, EPA concludes that the risks of aldicarb use would be significantly reduced to a level where they would no longer outweigh the remaining benefits. EPA has no reason to believe that the benefits of aldicarb are significantly greater in highly vulnerable areas than in less vulnerable areas. Thus, while regulatory actions to reduce the risk in vulnerable areas may have some effect on benefits, the overall effect of such actions should be to improve the balance of risks and benefits. EPA believes that the combination of measures recommended in this Notice would allow the continued use of aldicarb without unreasonable adverse effects on the environment.

F. Regulatory options

With the information available, EPA has developed three options it believes could be used to mitigate the contamination of ground water by aldicarb. These options were developed with the understanding that aldicarb use in a significant number of areas would result in ground water contamination at levels that would cause unreasonable adverse effects on the environment and that there are measures which are appropriate and could be implemented to prevent such contamination.

On February 26, 1988, EPA issued a proposed strategic plan for addressing ground water contamination by agricultural chemicals (*Agricultural Chemicals in Ground Water—Proposed Pesticide Strategy*, available for Environmental Protection Agency, Public Information Center (PM–211B), 401 M St. SW., Washington, DC 20460.) Options 2 and 3 were developed using the approaches discussed in the proposed strategy.

1. Option 1—Risk Reduction Measures/User Determines Applicability

This option reflects a registrant submitted application for amended registration which includes an extensive set of risk reduction measures. These risk reduction measures, which are detailed in the Technical Support Document, include drinking water well setbacks of 50 or 100 feet in various states (except where more stringent state requirements apply); limitations on use in certain soil types; modifications in application rate, frequency, and/or timing; monitoring of drinking water wells; and 6-month crop rotation restrictions. These measures would be targeted to the users and the costs of monitoring ground water contamination and corrective actions would be borne by the registrant. Preventive measures could be tailored to specific conditions of the application site in order to prevent contamination of drinking water wells in high or medium vulnerability areas.

If this option were adopted, it would include a comprehensive monitoring program which is designed to test a statistically significant number of sites where aldicarb is being used.

Different prevention measures would apply in different areas depending on the specific climatic and soil conditions associated with the application site. The risk reduction associated with this option may be considerable. Not only is there a substantial reduction in the likelihood that ground water will be contaminated, but there is also a provision for detecting any contamination which does occur.

The costs of this option could be considerable. The risk reduction measures themselves will result in increased costs in the use of aldicarb as well as a prohibition on its use on certain farms where it is now used or at certain times when it is now used without restrictions. There are additional costs associated with monitoring and implementing corrective action plans.

Additionally, the restrictions are very technical, requiring knowledge of such factors as soil types and temperature, and depth to ground water. EPA believes it will be difficult in some instances for growers to obtain this information and for states to determine whether the use of aldicarb is appropriate. However, EPA is prepared to accept the registrant's proposal to reduce the rate and frequency of application and restricting the period of time that aldicarb may be applied since these provisions are straightforward to interpret and, thus, generally easier to enforce.

Since ground water can be a potential drinking water source, simply protecting existing drinking water wells is insufficient because aldicarb could still reach the ground water. These modifications alone are not considered to be adequate to mitigate the potential for contamination of ground water above the Health Advisory.

2. Option 2—Labeling/Monitoring/State Management Plans Determined by Heath Region.

EPA has developed a second option which provides states the opportunity to

play an active role in protecting ground water. This option would better define those areas where the possibility of ground water contamination is the greatest and includes labeling modifications, monitoring of ground water, and establishment of State Pesticide Ground Water Management Plans (Management Plans) in certain states. In identifying which states would need to develop such plans under this option, EPA used the ground water assessment by Heath Region as described earlier. The components of this option are described in Units III.F.2.a. through 2.c.

a. *Labeling component.* The previous option considered labeling as the sole risk reduction measure. Option 2 considers labeling as one of several risk reduction measures, with increasingly stringent measures being used in increasingly vulnerable areas. Under this option, labeling would be a minimum requirement applicable to any use of aldicarb in any area of the country, regardless of whether the state or county in which it is used has a Management Plan. The label would prohibit application or mixing/loading operations of aldicarb within 300 feet of any drinking water well. States could set more stringent well setback requirements (including more stringent ones for public wells vs. private wells) if they so choose. EPA believes that this measure will serve to reduce contamination of drinking water because it reduces the likelihood that aldicarb will directly contaminate a drinking water supply. It is difficult to estimate the costs incurred from not using aldicarb in these areas since EPA has no basis to estimate the number of wells in areas treated with aldicarb. Some reduction in use is anticipated, but the impacts are not expected to be significant.

The label would also designate aldicarb as a restricted use pesticide due to ground water concerns. Aldicarb is already classified as a restricted use pesticide due to its acute toxicity. The ground water restriction would serve to heighten a certified applicator's awareness of the concerns regarding the possibility of ground water contamination and target aldicarb users for training using the newly-developed ground water educational module (soon to be available to the states). It is believed that this requirement would not significantly affect the costs of applying aldicarb.

EPA has considered additional site conditional measures that could be added to the label to deal with situations where leaching has been shown to occur. For example, EPA has information which demonstrates that leaching occurs when aldicarb is used on soils classified by the USDA Soil Conservation Service as "sand" or "sandy loam" and when the field overlies shallow ground water suitable for drinking, where shallow is defined as an average water table depth of less than 30 feet. A site specific measure prohibiting use of aldicarb in areas where these two conditions are met could be instituted. However, as discussed under Option 1, EPA has concerns whether this information is available to growers and whether these prohibitions are enforceable. Thus, EPA is not specifically proposing site conditional measures at this time but requests comment on their feasibility.

b. *Monitoring component.* The registrant would be required, under FIFRA section 3(c)(2)(B), to design and implement a monitoring program in representative areas rated as medium vulnerability to leaching. EPA would defer a proposal regarding the need for additional regulatory measures (e.g., requirement for implementing Management Plans) to manage the use of aldicarb in medium vulnerability areas until these additional monitoring data are submitted and assessed. This deferral is due to information available which suggests that medium areas are less susceptible to leaching than high vulnerability areas. EPA sees some potential for leaching in medium vulnerability areas in large part because of the variability of hydrogeological conditions. However, because of the limits on the understanding of this variability and how specific factors relate to leaching, EPA does not have as much basis for concern as in high vulnerability areas. Short of extensive mapping and advancement in scientific knowledge, EPA believes that monitoring would be the best way to understand the potential for aldicarb to leach in these medium vulnerability areas. In the interim period, the use of aldicarb in the medium vulnerability areas would be regulated through the labeling restrictions/prohibitions described in Unit III.F.2.

The costs associated with generating the monitoring data will not be considered part of the risk/benefit analysis as it is part of the expense involved in supporting the continued registration of this pesticide. The specific costs associated with a state implementing a Management Plan in medium vulnerability areas is not considered at this time since imposition of additional Management Plan requirements would necessitate a subsequent proposal.

c. *State Pesticide Ground Water Management Plan component.* EPA believes Management Plans provide the greatest site-specific assurances of proper use without overly protecting areas where contamination is unlikely. Management Plans put the primary responsibility on the state for regulating these specific areas and allows for evaluation of site-specific prevention measures based on the use, value and vulnerability of the ground water.

There are a number of approaches EPA could use in providing guidance to the states in developing a Management Plan. These various approaches range from establishing a performance standard based on a goal of preventing unacceptable contamination (i.e., the Maximum Contaminant Level or Health Advisory level) and allowing the states to develop a Management Plan to meet that standard, to providing a specific Management Plan which all states must adopt. EPA favors a middle path of providing a framework for the plan but providing flexibility to recognize that different states may use different approaches in accomplishing the same goal of protecting ground water from unacceptable contamination. However, each state would need to meet the performance standard through implementation of its Management Plan. EPA is seeking extensive comment on the design of a Management Plan and will be sponsoring a series of regional workshops beginning in the summer of 1988 to further explore and develop the concept. Anyone who wishes to comment specifically on the Management Plan presented by EPA should request a copy of the Aldicarb Technical Support Document from the contact person identified earlier in this Notice.

As envisioned by EPA, a Management Plan would be a comprehensive description of a state's approach for managing the use of a pesticide(s) for the purpose of protecting the ground water resource with specific attention given to preventing unacceptable contamination of current and potential drinking water supplies. The plan should:

(1) Describe the state's overall philosophy and approach to protecting its ground water from unacceptable pesticide contamination.

(2) List the specific measures to be employed (may include for example, one or more of the following: Cancellation of use or moratoriums; reduction in the rate of use; application method and timing limitations; more stringent well setback

restrictions; wellhead protection of public drinking water; mixing and loading requirements; changes in agronomic practices; permit or advance notice programs; and user education training.

(3) Identify the state's enforcement authorities and capabilities which can be used to assure compliance with the provisions of the plan.

(4) Identify the location of ground water that is currently and could potentially be a source of drinking water in the future or that is of ecological importance.

(5) Contain a monitoring scheme designed to ensure that the efforts to avoid contamination through proper use are effective or to identify contamination resulting from misuse/accident.

(6) Establish contingency plans to deal with contaminated ground water.

(7) In cases where contamination is at an unacceptable level, describe the mechanisms to be used to reduce contamination, including the source of funding.

(8) Describe how the public is kept informed and can become involved.

EPA realizes that there could be much variation among state plans to account not only for differing state conditions but also varying state approaches. EPA would be flexible in its review of the various state plans, recognizing that different approaches can be used to obtain the same goal (i.e., preventing contamination or reducing the likelihood of a pesticide in ground water reaching an EPA-designated level). States may elect to work collectively in developing various components of a plan; however, each state would be responsible for the development and implementation of its own plan.

Management Plans would be needed for those areas designated as having the greatest potential for aldicarb to reach ground water. As previously discussed, EPA used two methods of assessing the potential for ground water contamination. This option uses the Heath Region as the geographical unit for identifying states that would need a Management Plan.

Although EPA believes it would be advantageous for all states to implement a Management Plan, it realizes that such a requirement would be onerous for both states and EPA, at least until some states had experience in developing and implementing the plans.

To identify the states which most need to develop a Management Plan, EPA first identified the areas where there is the greatest possibility of ground water contamination resulting from the use of aldicarb. Those areas where potatoes are grown in the Northeast and Midwest and where citrus and peanuts are grown in the Southeast, have been identified using the Heath Region approach as having the greatest possibility of ground water contamination resulting from aldicarb use.

EPA then looked at the states which account for a large percent of the areas where aldicarb could be expected to be used the most and that contained a significant percent of the acreage of the crop (of the crop/Heath Region combination rated as highly vulnerable) in the high vulnerability areas.

Since potatoes grown in the Northeast and Midwest were rated as having a high vulnerability, to determine which states had the greatest number of acres within these Heath Regions, county totals of potato acreage from the 1980 Agriculture Census were summed. In those instances where a state is divided by a Heath Region, only the potato acreage within the two Heath Regions of concern was considered. Then, those states with the greatest potato acreage within the two Heath Regions of concern were identified.

It was determined that seven states (Maine, Michigan, Minnesota, New York, North Dakota, Pennsylvania, and Wisconsin) account for 98 percent of the potato acreage in the Northeast and Midwest. Further, three states in the Southeast (Alabama, Florida, and Georgia) account for virtually 100 percent of the peanut and citrus acreage within that region. Therefore, there are 10 states identified that would need to submit a Management Plan under this option (Alabama, Florida, Georgia, Maine, Michigan, Minnesota, New York, North Dakota, Pennsylvania, and Wisconsin). Other states in these regions with lower acreage would be covered by national labeling requirements and by monitoring requirements.

Additionally, as a condition for registration, the registrant would have to agree to monitor in high vulnerability areas where aldicarb is used and which are not subject to a Management Plan. Monitoring would be required in the states of Connecticut, Hawaii, Idaho, Illinois, Indiana, Kansas, Massachusetts, Missouri, Montana, Nebraska, New Hampshire, Ohio, Rhode Island, South Carolina, South Dakota, and Vermont, since some or all portions of these states are considered highly vulnerable.

This monitoring effort would involve sampling in fields where aldicarb is used. The wells to be sampled could either be suitable existing wells or specially constructed monitoring wells. Monitoring would be performed over a specified period of time and the data would be evaluated in order to assess the effect of the imposed labeling restrictions in terms of eliminating or reducing ground water contamination.

EPA has evaluated the possible costs for developing and implementing Management Plans in the 10 states. Estimates of the possible costs were developed from available published data where possible. For some cost components (e.g., number of wells affected, severity of contamination, exposed population, duration of contamination), data were not available to estimate the potential costs of requiring these plans. Furthermore, environmental and geographic conditions vary widely among and between the states needing to submit Management Plans. Without knowing in advance the measures each state may wish to employ to manage the use of aldicarb, precise estimates could not be developed. Recognizing the data limitations, EPA believes that the cost estimates are sufficiently accurate to serve as input in assessing initial economic effects.

Through conversations with state agencies that currently have management programs, it is estimated that the development and set up costs of a Management Plan could range from about $150,000 to $700,000 per state for the 10 states needing to submit Management Plans. These costs include the expenses associated with the actual development or structuring of the Management Plan ($10,000 to $25,000), construction of compliance monitoring wells including easements and land costs ($44,000 to $466,000), and mapping ($100,000 to $200,000). Development and set-up costs are a one-time expense.

The Management Plans would also have annual costs associated with implementation. These costs are estimated to range from $275,000 to $434,000 on a per state basis. These costs would include the expenses of such activities as enforcement, and sampling and analysis for aldicarb contamination. These costs would occur on a yearly basis but may decline if fewer samples are analyzed in later years or if voluntary compliance reduces enforcement costs. In its Management Plan, a state will define those conditions under which the use of aldicarb may be allowed. These include, for example: Banning the use in certain areas or under certain conditions, specifying how much aldicarb may be used on a per acre basis, or how many times aldicarb may be applied per year. EPA expects that the Management Plan will result in reducing the probability of ground water

contamination by aldicarb above the Health Advisory in the areas covered by the Management Plan and thus reduce the risk to an acceptable level.

In determining whether it is worthwhile to implement a Management Plan or allow use of aldicarb to be banned, one must consider the long-term rather than the short-term costs. Even though it has been estimated that the first year costs for the development, set up, and implementation of Management Plans in the 10 states could be as high as $6.17 million, $4.7 million would be one-time costs. Additionally, if other pesticides which leach require similar regulation in the future, some of the costs would already have been borne from regulating aldicarb. For example, the costs to develop a Management Plan do not occur on a yearly basis. Once a Management Plan is in place, it would be fairly easy to apply it to another pesticide which leaches. Similarly, although construction of compliance monitoring wells is fairly expensive, this is also a one-time expense. These wells may be used to determine whether other pesticides being applied in the same field are reaching the ground water.

Finally, if it is determined that the Management Plan were successful in eliminating the leaching of aldicarb into ground water, requirements for sampling, one of the more expensive yearly costs associated with implementation of a Management Plan, may be greatly reduced or eliminated. In addition, the potential costs of remedial actions which can range from several hundred dollars to more than $2,000 per household (annualized for 5 years), would also be eliminated if ground water was successfully protected from contamination.

The estimated cost resulting from cancellation in the 10 states assuming that a Management Plan were not developed, could exceed $60 million.

3. Option 3—Labeling/Monitoring/State Management Plans Determined by County. This third option is identical to Option 2 in that it would have the same labeling and monitoring components. However, the states that would need to develop Management Plans would be identified using a county approach which identified counties where EPA believes aldicarb has the highest tendency to leaching. Under this approach, states would need to develop and implement a Management Plan for those counties classified as such.

The criteria used to identify which counties would need a Management Plan are very similar to those used to select states in Option 2. The major difference is the size of the geographic area being analyzed. The criteria are hydrogeologic vulnerability, use/usage of aldicarb, and availability of positive monitoring data.

In the 4 states that EPA selected as examples for this assessment, California has 3 out of 58 counties, Florida has 26 out of 67 counties, and Wisconsin has 8 out of 72 counties needing a Management Plan. North Carolina did not have any counties which were ranked high enough to need the establishment of a Management Plan. However, the vulnerability to ground water contamination was sufficiently high in all other counties in each of these four states to be classified as medium in vulnerability. The registrant will be required to undertake a monitoring study that will be representative of those moderately vulnerable areas.

EPA has not completed an assessment of all counties within the United States. If this option is adopted, EPA would apply these criteria to all counties to identify those which need a Management Plan. Because the total number of counties needing a Management Plan is not yet identified, the costs resulting from a cancellation action under the county approach, assuming none of the states submit Management Plans for their county(ies), cannot be estimated at this time. However, EPA believes this cost would lie in the range of the costs associated with the Health Region approach and those resulting from cancellation of all aldicarb uses (i.e., between $60 million and $104 to $135 million).

The major problem with Options 2 and 3 is that some states may not have the legal authority, technical skills, or resources to establish or implement an effective Management Plan. Both approaches provide states a strong incentive to submit an acceptable Management Plan since, without it, use in the entire state or certain counties would be prohibited. In contrast to the county approach, the Health Region approach may be more likely to have areas that are either overly protected or underprotected since the classification of vulnerability was based on large Health Regions. The county evaluation was based on a more specific geographic unit, the county.

G. Proposed Regulatory Decision

EPA is deferring a decision regarding the potential risks due to dietary exposure to aldicarb from consumption of treated food commodities until the final results from the registrant's National Food Survey are evaluated. At such time, EPA will consider whether further regulatory action will be necessary.

EPA believes that ground water is a natural resource which must be protected from unacceptable contamination by pesticides. Data available to EPA confirm that aldicarb has a great leaching potential and that contamination of ground water above the Health Advisory has occurred in many instances. EPA's ground water assessment methods, using the Health Region or county approach, have examined areas of the country where aldicarb is used and have identified areas which are highly vulnerable to contamination. EPA believes that contamination above the Health Advisory is likely to occur at sites throughout these areas.

There are risks to people consuming drinking water contaminated by aldicarb above the Health Advisory. While EPA cannot predict the level of exposure to contaminated drinking water or the number of people exposed to such contamination, it is known that many have been contaminated by aldicarb. Available information suggests that the costs of correcting such contamination would be considerable. EPA concludes that on a national basis, the risks posed from contamination outweigh the benefits of use. Consequently, regulatory action to prevent ground water contamination is necessary to prevent unreasonable adverse effects on the environment.

EPA believes that it is possible to reduce the risks significantly by imposing certain regulatory restrictions short of cancellation of all use. These restrictions would be a graduated response to an area's vulnerability in such a way that the most stringent measures would be required in areas where there is the highest likelihood of unacceptable ground water contamination. EPA believes that such restrictions would reduce exposure to a point where the remaining benefits would outweigh the risks of use.

EPA has evaluated three options to prevent the unacceptable contamination of the nation's ground water by aldicarb and believes that Management Plans afford the greatest assurance of protecting ground water from contamination without overprotecting areas where contamination is unlikely or can reasonably be prevented. EPA further believes that it is necessary to impose certain restrictions on the use of aldicarb as a basic level of protection nationwide in order to reduce the potential for ground water contamination. Additionally, EPA does not believe that there are adequate data available to predict the likelihood of the

contamination of ground water in medium vulnerability areas.

Options 2 and 3 both accomplish these goals. They classify aldicarb as a restricted use pesticide due to its ground water contamination potential, in addition to its acute toxicity. They also provide a 300-foot well set-back on aldicarb use and require monitoring in medium vulnerability areas and Management Plans in the areas where ground water contamination is not likely to occur. Option 2 uses the Health Region approach in identifying the need to Management Plans on a state basis and Option 3 uses the county approach in identifying the need to Management Plans on a county basis. Because of the legal mechanisms established under FIFRA for accomplishing these goals, the alternative to establishing Management Plans in those states or counties where a Management Plan is needed but not implemented is cancellation of aldicarb use in those areas. EPA is seeking public comment as to whether Option 2 (state approach) or Option 3 (county approach) is favored.

EPA proposes Options 2 and 3 to impose label restrictions and monitoring requirements, and to allow the use of aldicarb in certain states/counties which have approved Managment Plans and cancel the use of aldicarb in certain states/counties which choose not to implement Management Plans.

In comparing the two options proposed by EPA, three basic differences are evident. Under Option 2, the state would need to implement a Management Plan which addresses all counties within the state rather than only specified counties as under Option 3. However, EPA recognizes that in addressing each county in a statewide plan, the state may properly conclude that only certain counties need to implement risk reduction measures. Another difference is the number of states which would need to implement a Management Plan. EPA estimated that the number of states which would need to implement a Management Plan under the approach in Option 3 will be between 15 and 24 compared to the 10 states identified under Option 2.

Finally, under Option 3, states would need to implement a Management Plan in all counties with a high potential to leach. Under Option 2, there are a number of states containing areas rated as having a high potential to leach (but with low aldicarb use) which would not need to implement a Management Plan. In these states the registrant, as a condition of registration, would be required to monitor ground water in high vulnerability areas to assure that the national uniform measures are sufficient to prevent ground water contamination at levels that would cause unreasonable adverse effects on the environment.

EPA is considering two different procedures for implementing the provisions of Options 2 and 3. Under one procedure, EPA would implement the Management Plan approach using the cancellation procedures in FIFRA section 6. In general, after appropriate opportunities for public and state participation, EPA would seek to cancel the use of aldicarb in areas where a Management Plan was considered necessary to prevent unreasonable adverse effects on the environment but for which areas no adequate Management Plan had been developed. As the first step of this process, once EPA decided how it would select the areas for which Management Plans are needed, it would explain the selection procedure, identify the areas, and establish a deadline for states to submit a description of their plans. Following EPA review and an opportunity for states to improve any plans which EPA might consider inadequate, EPA would issue a Notice of Intent to Cancel, identifying those areas in which cancellation would occur. Registrants and other adversely affected persons would then have an opportunity to challenge EPA's determinations in an adjudicatory hearing under FIFRA section 6.

Because the cancellation process is so lengthy and consumes so many resources, EPA is considering an alternative process. The alternative process would rely on the authority in FIFRA section 3(d)(1)(C) to issue regulations classifying a pesticide for restricted use and imposing "other regulatory restrictions" on its use. Generally, EPA would issue a proposed and final rule under FIFRA section 3(d)(1)(C) which restricted the use of aldicarb in section areas (e.g., the areas identified using Options 2 or 3) to use in conformity with a Management Plan. The regulations would establish requirements for the content of Management Plans, procedures for comment and review of Management Plans by EPA, and procedures for implementation by the states.

EPA requests public comment on these alternative procedures for implementing the Management Plan approach. EPA is particularly interested in comments addressing the time required for full implementation under each alternative. In addition, if the rulemaking approach is chosen, EPA is interested in the procedures that should be established for review and approval of Management Plans. Finally, EPA would be interested in other proposals on the process that should be used to implement a Management Plan approach.

EPA is seeking comment on whether site conditional measures should be required for aldicarb labels. A specific measure has not been proposed. EPA believes that unacceptable ground water contamination is likely to occur in certain situations, e.g., when applied to a certain soil type when the depth-to-ground water is less than a specified number of feet. Consequently, a label restriction prohibiting use of aldicarb in such instances would be useful in preventing unacceptable ground water contamination. However, given that a specific measure has yet to be identified, EPA cannot comment on the level of risk protection afforded or the cost impacts resulting from implementing this measure.

EPA is also soliciting public comment on the labeling requirement that aldicarb not be applied any closer than 300 feet of a drinking water well. Comment is specifically being requested on whether a 300-foot setback is appropriate, whether it should be a greater or lesser length, and whether there should be a different prohibition for public versus private wells. EPA is also interested in the anticipated impacts resulting from the proposed well setback in terms of decreases expected to yields.

In addition, because the regulatory approach recommended by EPA differs significantly from previous decisions under FIFRA, EPA requests comment on the way in which it has explained and supported its position. In particular, EPA invites public comment on the most appropriate analytical framework for weighing risks and benefits for a pesticide which has the potential to contaminate ground water. Should a more quantitative risk assessment be performed and, if so, how should it be performed? What should be included in the assessment (e.g., number of people exposed, cost of monitoring, treatment or clean-up, lost land values, value of potential drinking water)?

At what level of resolution should the benefits analysis be conducted (e.g., national, state, county, or local)? In making risk/benefit decisions on the county level, EPA could consider information such as the following:

1. The importance of aldicarb to the county, including the relative size of the contribution aldicarb-treated crops make to the local economy and additional local employment which depends on these crops (e.g., processing plants).

2. The importance of ground water to the county, including the extent to which the community depends on ground water as a drinking water source, the number of people who rely on private wells for drinking water, the degree to which this dependence is likely to change, and the importance of ground water in terms of projected land use (e.g., possible residential, commercial, or industrial development).

3. Management costs associated with mitigating the effects of the use of aldicarb in communities, including monitoring, point-of-use controls, importation of water, and clean-up costs.

4. The importance of conditions on efficacy of alternatives to aldicarb, including unique or special climatological or agronomic factors (e.g., age of citrus trees, amount and timing of rainfall).

5. Aldicarb's effectiveness and use (i.e., application rate by crop and county and usage), especially for high value (e.g., ornamentals), continuous cultivation crops (e.g., bananas), and crops with rapidly changing usage (e.g., soybeans).

EPA is soliciting comments on the appropriateness of the above factors, on additional factors which should also be considered, and on who should be responsible for developing this information. EPA also solicits comments on who should conduct the analysis (i.e., EPA or the states), and when the analysis should be performed. EPA proposes that outside parties (e.g., the registrant or user groups) interested in retaining the local use of aldicarb, will be responsible for gathering and providing local information needed to rebut EPA's presumption that risks outweigh benefits when the Health Advisory is exceeded.

EPA also requests comment on the analytical approaches it has used to identify the areas in which aldicarb use is most likely to contaminate ground water. In particular, EPA invites consideration of alternative criteria in applying the county-based analysis such as: setting the break points between high, medium, and low ratings for vulnerability at different DRASTIC scores, and giving a higher usage rating to counties in which root crops constitute a larger percentage of use. The criteria which have been used in this analysis are explained in detail in the Technical Support Document. EPA also invites comment on the break points which were used in determining which states need to implement a Management Plan for all or some of its counties.

EPA recognizes that the criteria used in assessing the potential for aldicarb to leach to the ground water and thus whether a county or state needs a Management Plan, create inconsistencies. For example, under the Heath Region assessment, counties which have a high potential to leach would not be subject to a Management Plan or monitoring by the registrant if the counties are not within a state which was part of a crop/Heath Region combination rated high in terms of potential to leach. Similarly, under the county assessment, various areas of a county may have a high potential to leach but the majority of the county has a medium potential to leach. Consequently, the use of aldicarb within that county would not be governed by a Management Plan.

EPA is also seeking comments in three other areas which are pertinent to the regulatory actions proposed. First, comments are being solicited on whether it is appropriate for the registrant to be involved in refining assessments regarding the likelihood of ground water contamination in an area and, if so, how such an assessment should be performed. The areas where such an assessment would occur should also be addressed. For example, instead of relying on a county's DRASTIC rating in a medium vulnerability area, the registrant could be required to assess vulnerability to leaching at the sub-county level, based on such factors as soil type, depth to ground water level, and location of crops which may be treated with aldicarb. This information would then be used as a part of the basis for determining whether a Management Plan would be needed.

EPA is also interested in obtaining additional information on the costs associated with the development and implementation of Management Plans. Another related issue EPA is concerned with is the level of involvement the registrant should have in developing Management Plans. Comments are being solicited both on the appropriateness of registrant involvement in developing Management Plans, and whether there should be a limit to their involvement.

Finally, EPA is soliciting comment regarding the issue of ground water contamination and liability. One unresolved question regarding ground water contamination is who should be responsible for remedial action (e.g. developing, approving, and implementing corrective action plans such as funding clean-up costs or providing an alternate water supply) when contamination results from a registered perticide use. EPA's proposed ground water strategy *(Agricultural Chemicals in Ground Water: Proposed Pesticide Strategy)* discusses this issue in more detail. Ground water contamination and liability is a generic issue which pertains to all pesticides which leach rather than just to aldicarb; consequently, any comments regarding this issue should be made in response to the above document and sent to Ground Water Strategy Project, Office of Pesticide Programs, U.S. Environmental Protection Agency (TS-767C), 401 M St., SW., Washington, DC 20460.

EPA recognizes that this Notice solicits comments on many issues which it will consider in making its final determination on aldicarb. Depending on the significance of these comments and how much EPA deviates from the actions proposed in this Notice, EPA may repropose regulatory actions prior to making its final determination.

V. Procedural Matters

A. Referral to the Secretary of Agriculture and the Scientific Advisory Panel

As provided in 40 CFR 153.31(b), EPA will transmit copies of this Notice and the Technical Support Document, to the Secretary of Agriculture and the Scientific Advisory Panel for comment. If either the Secretary or the Panel comments in writing on EPA's proposed action within 30 days of receipt of the draft Notice and supporting documents, EPA will publish any comments received from the Secretary or the Panel, and EPA's responses, in the Notice of Final Determination.

B. Procedures for Responding to Notice of Final Determination

Registrants, applicants, and other interested parties who would be adversely affected by any decision to cancel or deny applications for the registration of aldicarb products would be entitled to request a hearing in which to contest EPA's final decision to cancel registrations and deny applications for failure to comply with the modifications to registration listed in any final Notice of Intent to Cancel. Under FIFRA, such persons must submit their requests for a hearing within 30 days either following receipt of any final Notice of Intent to Cancel of Notice of Denial or following its publication in the **Federal Register**, whichever is later. As EPA will explain in detail in any final Notice of Intent to Cancel or Notice of Denial, a hearing request must contain information concerning the basis of the request. If a timely, properly formulated hearing request is submitted and a hearing is initiated, the product registrations which

are the subject of the request will remain in effect during the cancellation hearing. Similarly, applications for registration with respect to which valid and timely hearing requests have been filed remain pending unless and until they are denied or granted by order of the Administrator at the conclusion of the hearing.

If a proper and timely hearing request is not submitted for a product, registration of that product would be cancelled. A final cancellation would have the effect of prohibiting further sale and distribution except as specified in the existing stocks provision of the Notice.

It should be noted that registrants are not required to request a hearing at this time in order to be allowed to continue to sell and distribute their products within this period.

VI. Public Comment Opportunity

EPA is providing a 90-day period to comment on this Notice and on the Aldicarb Technical Support Document. EPA is particularly soliciting comments on the issues discussed in Unit IV of this Notice. Comments must be submitted by September 27, 1988. All comments and information should be submitted in triplicate to the address given in this Notice under **ADDRESS**, to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the indentifying notation OPP-30000/39A. All comments, information, and analyses which come to the attention of EPA may serve as a basis for final determination of regulatory action during the Special Review.

During the comment period, interested members of the public of registrants may request a meeting to discuss factual information available to EPA, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding aldicarb products. Persons interested in arranging such meetings should contact the Review Manager listed in this Notice under **FOR FURTHER INFORMATION CONTACT.**

VII. Public Docket

Pursuant to 40 CFR 154.15, EPA has established a public docket (OPP-30000/39A) for the Aldicarb Special Review. The public docket includes (1) this Notice; (2) any other notices pertinent to the Aldicarb Special Review; (3) non-CBI documents and copies of written comments or other materials submitted to the EPA in response to this Notice, and any other Notice, regarding aldicarb submitted at any time during the Special Review process by any person outside government; (4) a transcript of any public meeting held by EPA for the purpose of gathering information on aldicarb; (5) memoranda describing each meeting held during the Special Review process between EPA personnel and any person outside government pertaining to aldicarb; and (6) a current index of materials in the aldicarb public docket.

On a monthly basis, EPA will distribute a compendium of indices for newly received comments and documents that have been placed in the public docket for this Special Review. This compendium will be distributed by mail to those members of the public who have specifically requested such material for this Special Review, pursuant to 40 CFR 154.15(f)(3).

Dated: June 21, 1988.

John A. Moore,

Assistant Administrator, Office of Pesticides and Toxic Substances.

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